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## INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NUMBER CMT-0034 SERIAL NUMBER 10/560,374 FILED 12/12/2005

FIRST INVENTOR: Kyu Chan KWON TITLE STABLE, AQUEOUS SOLUTION OF HUMAN ERYTHROPOIETIN, NOT CONTAINING SERUM ALBUMIN

EXAMINER NYA

ART UNIT NYA

1. ☒ Applicant submits herewith a copy of (a) attached form PTO-1449, which lists all patents, publications, applications, or other information submitted for consideration by the Office; (b) a legible copy of each document required by 37 C.F.R. §1.98(b)(2).
2. ☐ Applicant herein apprises the Patent Office of references cited in a parent U.S. application from which this application obtains the benefit of an earlier filing date under 35 U.S.C. §120. The Serial Number of the parent application is U.S. Application \_\_\_\_\_ filed \_\_\_\_\_ and entitled \_\_\_\_\_.  
The publications cited therein are listed on attached Form PTO-1449. In accordance with 37 C.F.R. §1.98(d) copies of the listed publications are not required. ☐ Additional parent patent applications are listed on an attached sheet.
3. ☐ In accordance with 37 C.F.R. §1.98(a)(3), Applicant hereby certifies that for each reference not in English (check at least one box below):  
☐ A copy of a translation of one or more non-English document, or portion thereof, is provided herewith;  
☐ A concise explanation is (check at least one box below):  
☐ provided in the accompanying foreign or international search report; ☐ incorporated into the specification; and/or ☐ provided herewith.

### 37 C.F.R. §1.97(b)(1), (b)(2) – WITHIN 3 MONTHS OF FILING OR ENTRY IN NATIONAL STAGE

4. ☐ Since this Information Disclosure Statement is being filed within three months of the filing date of the subject application or within three months of the date of entry of the national stage as set forth in 37 C.F.R. §1.491 in an international application, no fee or certification under 37 C.F.R. §1.97(e) is required.

### 37 C.F.R. §1.97(b)(3), (b)(4) – PRIOR TO MAILING OF FIRST OFFICE ACTION OR FIRST ACTION AFTER REQUEST FOR CONTINUED EXAMINATION

5. ☒ Since this Information Disclosure Statement is being filed before the mailing date of the first Office Action on the merits, or before the mailing of a first Office action after the filing of a request for continued examination under 37 C.F.R. §1.114, no fee or certification under 37 C.F.R. §1.97(e) is required.

### 37 C.F.R. §1.97(c) – AFTER FIRST ACTION, BEFORE FINAL ACTION OR ALLOWANCE

6. ☐ Since this Information Disclosure Statement is being filed outside of the period provided for in 37 C.F.R. §1.97(b), but before the mailing date of a Final Rejection or Notice of Allowance, this submission is being accompanied by (one of the following boxes must be checked):
  - a. ☐ the fee required under 37 C.F.R. §1.97(c)(2) and specified in 37 C.F.R. §1.17(p).
  - b. ☐ the statement specified in 37 C.F.R. §1.97(e) (Box 8 or 9 must be checked).

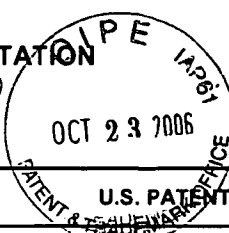
### 37 C.F.R. §1.97(d) – AFTER FINAL REJECTION OR ALLOWANCE

7. ☐ Since this Information Disclosure Statement is being filed after the period specified in 37 C.F.R. §1.97(c), but on or before payment of the issue fee and is accompanied by both the statement specified in 37 C.F.R. §1.97(e) and the fee set forth in 37 C.F.R. §1.17(p). (Box 8 or 9 must be checked.)
8. ☐ In accordance with 37 C.F.R. §1.97(e)(1), Applicant's attorney certifies that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. ☐ The foreign or international search report(s) is/are enclosed.
9. ☐ In accordance with 37 C.F.R. §1.97(e)(2), Applicant's attorney certifies that no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this certification after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of the information disclosure statement.
10. ☒ In the event the Commissioner of Patents deems that any additional fee is required under 37 C.F.R. §§ 1.16 or 1.17 in connection with this application, Applicant's attorneys authorize that such fee be charged to Deposit Account No. 06-1130.
11. Consideration of this Information Disclosure Statement is respectfully requested.

Name:	<u>Jae Y. Park</u>	Registration Number	<u>L0077</u>
Signature		Date	<u>10-19-2006</u>

CERTIFICATE OF MAILING OR TRANSMISSION: I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner For Patents, P.O. Box 1450, Alexandria, VA 22313-1450, or [ ] facsimile transmitted to the U.S. Patent and Trademark Office to Facsimile No. \_\_\_\_\_ on the date shown below.

Name	<u>Desiree Bobo</u>		
Signature		Date	<u>10-19-2006</u>

<b>INFORMATION DISCLOSURE CITATION</b> <i>(Use several sheets if necessary)</i>				ATTY DOCKET NO. <b>CMT-0034</b>		APPLICATION NO. <b>10/560,374</b>	
				APPLICANT(S) <b>Kyu Chan KWON</b>			
				FILING DATE <b>December 12, 2005</b>		GROUP ART UNIT <b>1647</b> <del>NTA</del>	
				U.S. PATENT DOCUMENTS			

*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
/RMD/	4,992,419	2-12-1991	WOOG, et al.	514	8	9-1-1988
	6,303,113	10-16-2001	WOOG, et al.	424	85.1	1-30-1996
	5,661,125	8-26-1997	STRICKLAND	514	8	5-24-1995
	5,376,632	12-27-1994	KONINGS, et al.	514	8	6-30-1992
/RMD/	4,806,524	2-21-1989	KAWAGUCHI, et al.	514	8	10-3-1985

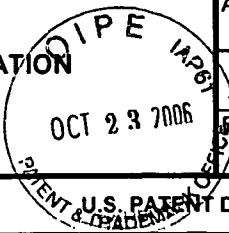
U.S. PATENT APPLICATION PUBLICATIONS						
*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
/RMD/	2002/0037841	3-28-2002	PAPADIMITRIOU	514	8	5-11-2001

FOREIGN PATENT DOCUMENTS								
*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION		
						YES	NO	
/RMD/	00/61169	10-19-2000	PCT				✓	
	85/02610	6-20-1985	PCT				✓	
	01/87329	11-22-2001	PCT				✓	
/RMD/	0909564	4-21-1999	EUROPE				✓	

OTHER DOCUMENTS <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>			
/RMD/			<b>"OVERVIEW OF THE STABILITY AND HANDLING OF RECOMBINANT PROTEIN DRUGS; Author: John Giegert; Journal of Parenteral Science &amp; Technology, vol. 43, No. 5; 220-224, 1989</b>
/RMD/			<b>"BLOOD"; Author: Sanford B.K.; Journal of the American Society of Hematology, vol. 77, No. 3; 419-434, 1991</b>

<b>EXAMINER</b> /Regina DeBerry/ (09/12/2008)	<b>DATE CONSIDERED</b>
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<b>INFORMATION DISCLOSURE CITATION</b> <i>(Use several sheets if necessary)</i>				ATTY DOCKET NO. <b>CMT-0034</b>		APPLICATION NO. <b>10/560,374</b>		
				Kyu Chan KWON		GROUP ART <b>1647</b> <del>NYA</del>		
				FILING <b>December 12, 2005</b>				
<b>U.S. PATENT DOCUMENTS</b>								
*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
/RMD/		4,879,272	11-7-1989	SHIMODA, et al.	514	8	10-4-1985	
<b>U.S. PATENT APPLICATION PUBLICATIONS</b>								
*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
<b>FOREIGN PATENT DOCUMENTS</b>								
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>								
/RMD/		"INSTABILITY, STABILIZATION, AND FORMULATION OF LIQUID PROTEIN PHARMACEUTICALS"; Author: Wei Wang; International Journal of Pharmaceutics; 185, 129-188, 1999						
/RMD/		"CORRECTION OF THE ANEMIA OF END-STAGE RENAL DISEASE WITH RECOMBINANT HUMAN ERYTHROPOIETIN"; Author: Eschbach, et al.; New England J. Med. vol. 316, No. 2; 73-78; 1987						
<b>EXAMINER</b>				<b>DATE CONSIDERED</b>				
/Regina DeBerry/ (09/12/2006)								
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*(Use several sheets if necessary)*

PIPE 14281  
 TATION  
 OCT 23 2006  
 OFFICE  
 (Including Author, Title & Trademark)

**Application Number**  
**10/560.374**

**Filing Date**  
**December 12, 2005**

Group Art Unit 1647

**OTHER DOCUMENTS** (Including Author, Title, Date, Pertinent Pages, Etc.)

/ BMD /

**"INFLUENCE OF SURFACTANTS UPON PROTEIN/PEPTIDE ADSORPTION TO GLASS AND POLYPROPYLENE";**  
**Author: Duncan, et al.; Int. J. Pharm.; 120; 179-188, 1995**

**"PURIFICATION OF HUMAN ERYTHROPOIETIN"** Author: Miyake, et al.; J. Biol. Chem. vol. 252; No. 15; 5558-5564, 1997

**"ADSORPTION OF PROTIENS FROM SOLUTION AT THE SOLID-LIQUID INTERFACE"; Author: Willem Norde; Adv. Colloid Interface Sci. vol. 25; 267-341, 1986**

**"PHARMACEUTICAL EXCIPIENTS FOR THE STABILIZATION OF PROTEINS"; Author: David Wong,et al.; Pharm. Tech.; 34-50; October 1997**

/BMD/

**EXAMINER**

/Regina DeBerry/ (09/12/2008)

**DATE CONSIDERED**

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